Cc: Orme-Zavaleta, Jennifer[Orme-Zavaleta.Jennifer@epa.gov]; Yamada, Richard
(Yujiro)[yamada.richard@epa.gov]
From: Rodan, Bruce
Sent: Tue 1/2/2018 4:26:16 PM
Subject: FW: Federal Register Notices for your review and signature
1C Memo FRN Protocol chloroform.docx
2C 2016 Action Information Template - IRIS Chloroform Protocol.docx
3C FRN IRIS Chloroform Protocol.docx
4C Yamada FRN approval memo FRN IRIS IAP Chloroform 12-21-17.docx
5C_IRIS-Protocol-chloroform_12-14-17_clean.docx
1U Memo FRN IAP uranium.docx
2U 2016 Action Information Template - IRIS Assessment Plan for Uranium.docx
3U FRN IRIS IAP Uranium.docx
4U Yamada FRN approval memo FRN IRIS IAP Uranium 12-21-17.docx
5U_Uranium updated IAP IOAA FR Notice approval version.docx
Tina, Kris,
Hi. Welcome to the New Year! Jennifer, Richard, and I spoke this morning, and had a few process questions regarding the Chloroform protocol FRN, since it contains quite a deal of information on the Systematic Review Protocol and decision language – and appears to be of major importance in the lead-up to an NAS review:
•□□□□□□□ What has been the intraAgency process so far on the chloroform FRN?
•□□□□□□□□ If not circulated intraAgency as an FRN, what has been the IntraAgency process on the systematic review protocol and standard decision tables/language in the Chloroform FRN?
• □ □ □ □ □ □ □ A substantial proportion of the FRN reminds me of the detail in the IRIS SOPs. There was some intraAgency angst in the past regarding the language being proposed to summarize non-cancer findings/classifications. This FRN has a detailed "Framework for classification of strength of evidence from studies in humans", as well as Frameworks for evaluating the strength of PBPK modeling. Were these the areas of intraAgency concern, and have these concerns been addressed agency-wide?
• • • • • • • • • • • • • • • • • • •

Bahadori, Tina[Bahadori.Tina@epa.gov]; Thayer, Kris[thayer.kris@epa.gov]

To:

•□□□□□□□ More speci	ifically, has OCSI	PP been apprised	of these protocols	during intraAgency
review or subsequently?	Could this FRN	come as a surpris	se to OCSPP or an	other Program?

Thanks

Bruce D. Rodan

Associate Director for Science

U.S. EPA, Office of Research and Development

From: Bahadori, Tina

Sent: Thursday, December 21, 2017 7:07 AM

To: Orme-Zavaleta, Jennifer < Orme-Zavaleta. Jennifer@epa.gov>; Yamada, Richard (Yujiro)

<yamada.richard@epa.gov>

Cc: Ross, Mary <Ross.Mary@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>; Soto, Vicki <Soto.Vicki@epa.gov>; Shams, Dahnish <Shams.Dahnish@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>; Christian, Megan <Christian.Megan@epa.gov>; Kuhn, Kevin

<Kuhn.Kevin@epa.gov>; Blackburn, Elizabeth <Blackburn.Elizabeth@epa.gov>; Rodan, Bruce

<rodan.bruce@epa.gov>; Fleming, Megan <Fleming.Megan@epa.gov>

Subject: Federal Register Notices for your review and signature

Good Morning Jennifer and Richard,

We are preparing to release for public comment an IRIS Assessment Plan for (non-radiological) Uranium and a Protocol for Chloroform. Both of these were among the portfolio of 'targeted' assessment products presented to the SAB-CAAC in September as examples of assessments we can do relatively quickly because the partner need is focused and 'bounded.' For each chemical, we have attached the following documents – C and U in the name of the attachment denote Chloroform and Uranium respectively:

- 1. A memo that summarizes the effort for you
- 2. Action Information that accompanies the FR Notice
- 3. The FR Notice
- 4. FRN Approval Form (requires Richard's signature)
- 5. The document an Assessment Plan or a Protocol

If you have any questions or would like additional information, please do not hesitate to give me a call.

Many thanks,

Tina

Tina Bahadori, Sc.D.

Director, National Center for Environmental Assessment (EPA/ORD/NCEA)

National Program Director, Human Health Risk Assessment (EPA/ORD/HHRA)

RRB Room 71210; Telephone: 202-564-7903; Mobile: 202-680-8771